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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,242	11/09/2001	Michelle Lu	680.0043USU	9256

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EXAMINER

GHALL, ISIS A D

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/040,242

Applicant(s)

LU ET AL.

Examiner

Isis A. Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 19-234 is/are pending in the application.
- 4a) Of the above claim(s) 11,12 and 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10,13-16 and 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 11/06/2006.

Claims 17 and 18 have been canceled, and claims 30-34 have been added.

This application contains claims 11, 12, 19-24 drawn to a nonelected invention in the response filed 04/28/2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-10, 13-16, and 25-34 are included in the prosecution.

The following rejection have been overcome by virtue of applicants' amendment and remarks:

(A) The rejection of claims 1-10, 13-16, and 25-29 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

(B) The rejection of claims 1-10, 13-16, and 25-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-10, 13-16, and 25-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment made to claims 1 and 13, as well as newly added claim 34 includes new matter by reciting "consisting essentially of". Nowhere applicants have disclosed composition consisting essentially of "a broth having cultured, homogenized, substantially undifferentiated plant seed cells and vehicle". All the examples include other materials that could have cell proliferation effect. Additionally, nowhere applicants have disclosed "amount effective to increase cell proliferation". On pages 10 and 11 of the present specification, applicants disclosed that "a topical composition having plant seed cells can have active ingredients that improves the aesthetic and/or cosmetic appearance of skin.....such improvement can be manifested inincrease in skin cell proliferation". Therefore, no disclosure of "a broth having cultured, homogenized, substantially undifferentiated plant seed cells in

Art Unit: 1615

an effective amount effective to increase cell proliferation" as recited by claims 1, 13, and 34. Hence, the increase of skin cell proliferation is not disclosed as an effect of the plant seed cells alone, it is an effect or function of additional ingredients. Furthermore, applicants themselves admit that the transitional phrase "consisting essentially of" limits the scope of the claim to the specified materials or steps that do not materially affect the basic and novel characteristics of the claimed invention. However, the claimed composition comprises vehicles that can have effect on the skin proliferation such as vegetable oils and mineral oils, etc.

3. Claims 31 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reduction in dermatological signs of aging, does not reasonably provide enablement for preventing skin atrophy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the

Art Unit: 1615

examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is and method of preventing skin atrophy using composition comprising a broth having cultured, homogenized, substantially undifferentiated plant seed cells in an effective amount effective to increase cell proliferation, and vehicle. Nowhere in the specification applicant showed prevention of skin atrophy. Further, the specification does not enable the prevention of the skin atrophy in susceptible patients.

The breadth of the claims: The claims are very broad. The claim encompasses prevention of skin atrophy in susceptible patients, and the burden of enabling prevention of skin atrophy would be greater than that of enabling a treatment due to the need of additional testing and screening to those humans susceptible to such skin atrophy that is controlled by many factors such as age, occupation, life style, etc. The prevention of skin atrophy may or may not be addressed by the administration of the instant composition.

The state of the prior art: The state of the art does not recognize the administration of compositions to prevent dermatological disorders such as skin atrophy. The state of the art recognizes the treatment of dermatological disorders. See WO 00/64472.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The guidance given by the specification on how to prevent skin atrophy is absent. Guidance for treatment of signs

Art Unit: 1615

of aging is provided, however, no evidence is provided that skin atrophy is prevented. It is not obvious from the disclosure of treating signs of aging using the claimed composition that the same composition will work in preventing skin atrophy. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the limitations fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of significant guidance from the specification or prior art with regard to completely preventing skin atrophy by using the instant composition makes practicing the claimed invention unpredictable in terms of the prevention of the skin atrophy.

The presence or absence of working examples: The specification and example 1-5 discloses composition comprising undifferentiated plants cell. No working examples to show skin atrophy have been prevented. Therefore, the specification has not enabled prevention of skin atrophy.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant method for preventing skin atrophy without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

4. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '878 in view of WO 472 , and further in view JP 06-298695 ('695).

Art Unit: 1615

The combined teaching of the references is discussed in section 7 of the office action. However, the combined teaching does not teach the preservation of the broth or the spray drying of broth to form a powder.

JP '695 teaches cosmetic composition comprising plant sprouts that is freeze-dried and grounded (abstract; paragraphs 0012-0016).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical composition comprises cultured plant seed cells as disclosed by the combined teaching of US '878 and WO '472, and further freeze-dry and grind the resultant as disclosed by JP '695, motivated by the teaching of JP '695 that such grinded freeze-dried sprouts are suitable for cosmetic, with reasonable expectation of having topical composition comprising grinded freeze-dried cultured plant cells that are delivered to the skin successfully.

The following rejection has been discussed in the previous office action, and is maintained for reasons of record:

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-10, 13-16, and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0071878 ('878) in view of WO 00/64472 ('472).

US '878 teaches a topical composition comprising homogenized cultured seed cells obtained from cucumber and carrot that used in cosmetic and dermatological compositions (abstract; page 3, 0029-0031, page 4, table 2; page 5, 0038, 0039, 0041; page 10, 0137; page 11, 0143, 0144; page 17, claim 10). The composition is in the form of gel, cream and comprises acceptable vehicle and selected from polyethylene glycol, oils, silicone oil, or fatty acids (page 10-11, 0137). The composition used to treat skin disorders such as hirsutism, reduction of nail growth, hair treatment, inhibition of scar formation (page 18, claim 22).

However, US '878 does not teach the culture media is broth that has broad range of plant cell constituents as claimed in claims 1 and 13, the amount of the plant seed cells in the composition as claimed in claims 2-5, 7, 15 and 16, the specific plants used

in the composition as claimed in claims 6, 14, 25-29, and the specific skin conditions treated by the composition.

Applicants do not show superior and unexpected results obtained from using the broth as culture media. US '878 disclosed that any culture media will be suitable, paragraph 0038. The broad range of plant cell constituents is expected to be present in any cultured cell depending on plant species once the cells placed in culture media.

According to the intended use and the site of application, one having ordinary skill in the art would manipulate the amount of the cultured seed cells in the composition in order to achieve a beneficial effect. The claimed amounts do not impart patentability to a composition comprising undifferentiated plant seed cells, absent evidence to the contrary. Also selection of specific seeds is within the skill in the art depending on the specific use.

WO '472 teaches a method and composition for treating dermatological conditions using fruit extract, with the extract from pomegranate is preferred (abstract). The composition used to treat age spots, reduced skin moisture, deepening of skin lines, blemished skin and impetigo (page 11, lines 7-10). The amount of the fruit extract in the composition ranges from 0.1 to 20% (page 11 lines 15-16). The extract can be from the seed (page 11, line 24). The composition comprises a vehicle as oils and is in the form of gel or cream (page 12, lines 1-15, page 25, lines 26-30).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the composition comprising cultured plant seed cells in a topical composition to treat skin disorders as disclosed by US '878, and to select the

Art Unit: 1615

specific plant seeds depending on the condition to be treated as disclosed by WO '472, motivated by the teaching of WO '472 that the fruit extracts manage dermatological conditions related to aging, with reasonable expectation of having a topical composition that provides the cultured plant seed cells to the skin, nails or hair at the desired amount to a particular location with disorder and in need for the such a treatment with success.

Response to Arguments

8. Applicant's arguments filed 11/06/2006 have been fully considered but they are not persuasive. Applicants traverse the rejection of the pending claims over US '878 in view of WO '472 by arguing that:

- Claims 1, 13 as amended to recite "consisting essentially of" intended to substantially foreclose the presence of differentiated plant seed cells that required by US '878.

In response to this argument, applicants attention is directed to the scope of the present claim that is directed to composition comprising undifferentiated plant seed cells and vehicle, and the elements of the composition are taught by US '878. The claims recite the composition "increase cell proliferation", although it is not clear which cells: skin cells or plant cells?, however, applicants disclosed increase skin proliferation to reduce of signs of aging and US '878 teaches reduction of signs of aging. It is expected to have undifferentiated cells once the seeds are cultured in any culture media, thus, the cultured seeds disclosed by US '878 are undifferentiated. The expression "consisting

Art Unit: 1615

essentially of" limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition. *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference's composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of the claimed composition, i.e. showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte*, 337 F 2d 870, 143 USPQ 256 (CCPA 1964). The claims' language permits the presence of some differentiated cells that does not materially alter the composition. The claimed composition used to increase cell proliferation to combat signs of aging and to improve the aesthetic appearance of the skin, and US '878 teaches on claim 19, page 18, that the topical composition used for maintenance of juvenile skin appearance and for treatment of age-related phenomenon of the skin. US '878 teaches cosmetic topical composition as instantly claimed, comprising undifferentiated seed cells, and used for the same purpose as applicants.

- Applicants argue that US '878 disclosed inhibition of growth and proliferation of target cells, and not increase cell proliferation to improve aesthetic appearance of the skin as instantly claimed.

In response to this argument, it is noticed that US '878 teaches on claim 19, page 18, that the topical composition used for maintenance of juvenile skin appearance and for treatment of age-related phenomenon of the skin, and what applicants have done. In considering the disclosure of the reference, it is proper to take into account not only the

Art Unit: 1615

specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

- Applicants argue that WO 472 discloses a skin composition containing fruit extract and not plant seed cells, therefore, no motivation to combine the cited references.

In response to this argument, the examiner position is that WO '472 is relied upon for the sole teaching of the suitability of different seed extracts in cosmetics, therefore, since the art recognized using the cultured cells, then these seeds useful as an extract would be used also as cultured. The rationale to modify the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art and the reason to modify the reference may often suggest what the applicant has done. The invention as a whole is disclosed by the references in combination. The art recognized topical composition comprising cultured seeds, and a conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1615

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Primary Examiner
Art Unit 1615
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A handwritten signature in cursive script, appearing to read "Isis Ghali", followed by a period.